

REMARKS

Claims 1-23 are pending. No amendments have been made by way of the present submission, thus, no new matter has been added.

In the outstanding Office Action the Examiner has asserted that the application contains Groups of Invention which are not so linked as to form a single general inventive concept under PCT Rule 13.1. Thus, the Examiner has requested that Applicants elect one of the following two groups:

Group I, claim(s) 1-19, drawn to an orally administrable composition containing nanoparticles.

Group II, claims (s) 20-23, drawn to a method for preparing the orally administrable nanoparticles composition.

Applicants respectfully traverse the Examiner's Unity of Invention Rejection. The Examiner has asserted that the groups listed above do not relate to a single general inventive concept because they lack the same or corresponding special technical feature. The Examiner asserts that the technical feature of Group I is orally administrable nanoparticles composition which is allegedly shown by Sakuma, et al., 2001, Advanced drug delivery review, 47, 21-37.

Applicants submit that this an unnecessarily narrow characterization of the present invention. In particular, one purpose of the present invention is to provide an orally administrable composition containing nanoparticles with a particle size of 500 nm or less, comprising 0.1-30 weight % of a complex of water-soluble drug and a counter-ion substance in which the charged water-soluble drug is bonded with the counter-ion substance, 0.5-80 wt% of a lipid, 0.5-80 wt% of a polymer, and 1-80 wt% of an emulsifier, wherein the weight ratio of the lipid and the polymer is in the range of 1:0.05-3. Such subject matter is absent from Sakuma cited by the Examiner. As such, Applicants respectfully submit that the presently pending claims share unity of invention.

However, in order to be fully responsive to the outstanding Unity of Invention Rejection Applicants hereby elect Group I. This is an election with traverse as noted above.

Applicants further hereby reserve the right to request rejoinder of the non-elected process claims so long as all limitations of an allowable product claim are recited therein.

The Examiner has also required an election of species. This specific election of species is set forth of pages 4 and 5 of the outstanding Office Action. In response thereto, Applicants provide the follow elections of species:

No.	Species	Election
1.	1-5, 9, 10, 20 & 22 Water-soluble drug	Insulin
2.	1, 6, 7, 9, 10 & 20 Counter-ion substance	Sodium salt of C8-C18 fatty acid
3.	1, 11, 12 & 20 Lipid	monoglyceride
4.	1, 13 & 20 Polymer	Methacrylic acid copolymer
5.	17 & 18 Cryoprotecting agent	mannitol
6.	1, 14, & 20 Emulsifier	Polyoxyethylene polyoxypropylene copolymer
7.	22 pH adjusting agent	Citric acid

It is Applicants' understanding that the above elections of species will simply serve as starting points for search and examination purposes. Upon indication of allowable subject matter for the elected species, the Examiner must expand the search to include other non-elected species with the intent of finding the generic claims ultimately allowable.

Additionally, Applicants take this opportunity to point out that the technical feature of the present invention is containing nanoparticles with the particle size of 500 nm or less and adding specific wt% ranges of complex of water-soluble drug and a counter-ion substance, lipid, polymer and emulsifier, and not necessarily in the selection of the specific kinds of water-soluble drug, counter-ion substance, lipid, polymer and emulsifier. Thus there should be no need to restrict the above materials to their specific types. Further, a cryoprotecting agent and pH adjusting agent are additional components, and therefore, there should also be no need to restrict these components to their specific types.


In view of the above, favorable action on the merits is respectfully solicited.

If the Examiner has any questions or comments, please contact Craig A. McRobbie, Reg. No. 42,874 at the office of Birch, Stewart, Kolasch & Birch, LLP.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to our Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under § 1.17; particularly, extension of time fees.

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Respectfully submitted,

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